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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,213	02/08/2000	Mark G. Schrom	16724-108	2262

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/500,213

Applicant(s)

SCHROM ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/28/03 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43, 44, 52, 53, 57, 59, 60, 63, and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwaszkiewicz et al (4590950). The recitation of “electroplated” or “electroplating process” in the claims is more like a method step directed to how the links are produced rather than a structural limitation and Iwaszkiewicz’s links, 20, are structurally equivalent to the claimed links. In addition, Iwaszkiewicz shows the use of conductor 19 extending substantially the length of the body member and connecting to electrode 11 through two links, 20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 54 and 66 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Iwaszkiewicz. Iwaszkiewicz has the width of the electrode, 11, as 0.3 mm (2.3 mm OD - 2.0 mm ID) and therefore is a thin film electrode. In addition, the first and second segments of the electrode is the proximal and distal segments of the electrode. Also, the conductors are shown spiraled at an angle of about 80 degrees.

In the alternative, Iwaszkiewicz discloses the claimed invention except for the thin film electrode and conductors spiraled at about 10 to about 80 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical lead as taught by Iwaszkiewicz, with the thin film electrode and conductors spiraled at about 10 to about 80 degrees since it was known in the art that medical leads use thin film electrodes to provide a small, flexible lead that is easily inserted into the body and since it was known that medical leads use conductors spiraled from about 10 to about 80 degrees to provide greater or lesser torque and flexibility to the leads.

Claims 45-50, 56, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaszkiewicz et al. For claims 48, 49, 50, Iwaszkiewicz discloses a thin film electrode with the conductor being stainless steel or MP35N and spiraled at an angle of about 80 degrees. In the alternative, see the 103 rejection given in the preceding paragraph.

Iwaszkiewicz discloses the claimed invention except for the first conductor being embedded in the annular wall (claims 45, 56, and 61), the outer diameter of the lead being about 2 French and internal diameter being 0.012 inch (claim 46), and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high (claim 47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught Iwaszkiewicz, with the conductor being embedded in the annular wall, an outer diameter of the lead being about 2 French and internal diameter being 0.012 inch, and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high, since it was known in the art that leads have: conductors embedded in the annular wall to ensure stability of the conductors and overall strength of the lead; an outer diameter of the lead being about 2 French and internal diameter being 0.012 inch to allow the lead to be unobtrusively placed in small areas of the body and to prevent tissue damage and irritation; and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high to provide a small diameter lead with flexibility in particular directions.

In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Iwaszkiewicz with the outer diameter being about 2 French and internal diameter being 0.012 inch and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high, because Applicant

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has not disclosed that the outer diameter being about 2 French and internal diameter being 0.012 inch and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high, provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the thin electrode lead having circular conductors in a helical pitch as taught by Iwaszkiewicz because it will provide a small body implantable flexible lead that is easily and quickly produced.

Therefore, it would have been an obvious matter of design choice to modify Iwaszkiewicz to obtain the invention as specified in the claim(s).

Claims 51, 58, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaszkiewicz in view of Willis, 5433742 (or Gotthardt et al, 5016646).

Iwaszkiewicz discloses the claimed invention except for the conductive links being a conductive epoxy. Willis (or Gotthardt) teaches that it is known to use a conductive epoxy to provide a good mechanical and electrical connection between the conductors and electrode. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical lead as taught by Iwaszkiewicz, with the conductive links being a conductive epoxy as taught by Willis (or Gotthardt), since such a modification would provide a medical lead with conductive links being a conductive epoxy to provide a good mechanical and electrical connection between the conductor and electrode.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaszkiewicz.

Iwaszkiewicz discloses a thin film electrode. In the alternative, see the 103 rejection above.

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Iwaszkiewicz discloses the claimed invention but does not disclose expressly the thin film electrode comprising a first layer of titanium, chromium, etc of 5 microns and a second layer of gold, platinum, etc of about 500 angstroms to about 50 microns. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the medical lead as taught by Iwaszkiewicz, with the thin film electrode comprising a first layer of titanium, chromium, etc of 5 microns and a second layer of gold, platinum, etc of about 500 angstroms to about 50 microns because Applicant has not disclosed that the thin film electrode comprising a first layer of titanium, chromium, etc of 5 microns and a second layer of gold, platinum, etc of about 500 angstroms to about 50 microns provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the thin electrode as taught by Iwaszkiewicz, because it provides a thin, small electrode that is easily inserted into the body.

Therefore, it would have been an obvious matter of design choice to modify Iwaszkiewicz to obtain the invention as specified in the claim(s).

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaszkiewicz.

Iwaszkiewicz discloses the claimed invention except for the duplication and connection of the conductors, tunnels, links, and electrode to provide a second electrode. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical lead as taught by Iwaszkiewicz, with a second duplicate connection of conductors, tunnels, links, and electrode to provide a second electrode since it was known in the art that medical leads use more than one electrode to provide stimulation/therapy to different areas of the

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body with only one lead. In addition, it has been held that duplication of parts is obvious to one having ordinary skill in the art at the time the invention was made (In re Harza, 124 USPQ 378).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.


George R Evanisko
Primary Examiner
Art Unit 3762

9/22/3

GRE
September 23, 2003